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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,601	02/14/2006	Peter Klapproth	KLAPPROTH	9583

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HENRY M FEIEREISEN, LLC
350 FIFTH AVENUE
SUITE 4714
NEW YORK, NY 10118

EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
10/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,601	KLAPPROTH ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declaration do not have the correct statement with respect to the duty to disclose.

CORRECT STATEMENTS should read:

- "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

INCORRECT STATEMENTS:

- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56"

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 recites the limitation "the temporal course" in line 13. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite and unclear if the "memory module" in line 13 and the "memory unit" in line 15 are the same element or are separate from each other.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 20-27, 29, 30 and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Franberg et al. (US Patent no. 5,271,396).

In regard to claims 20 and 39, Franberg et al. disclose an activity controlled pacer 1 that comprises a pulse generator unit 3 for generating and supplying electric stimulation pulses, col 3 lines 48-50; a control unit 6 for controlling the pulse generator unit for setting an amplitude and a frequency of the stimulation pulses and for causing the stimulation pulses to be applied to a muscle to be stimulated, col 3 lines 51-54; a detection unit 27 for detecting an instantaneous, spontaneous or stimulated heart rhythm of a wearer of the device, col 5 lines 19-21; a housing 8 (i.e., enclosure) receiving the pulse generator unit, the control unit and the detection unit; a memory module for storing the temporal course defined by timers 20 and 21 of the number of supplied stimulation pulses within a defined time interval; a counting unit 32 and a memory unit for counting and storing a number of stimulation pulses supplied during the defined time interval, wherein the stimulation pulses are grouped into variable stimulation bursts, col 6 lines 10-13; a determination unit 14 (i.e., the evaluation stage) for determining an arithmetically averaged (mean) stimulation frequency within the defined time interval, with the mean stimulation frequency being computed as the quotient of the number of stimulation pulses of the variable stimulation bursts supplied during the defined time interval and stored in the memory unit and the defined time interval in which the stimulation pulses are counted and stored, col 2 lines 47-51, 60-63, col 4 lines 14-24 and col 5 lines 64-67; the determination unit 14 (i.e., the evaluation

stage) further is configured for continuously operating evaluation unit for ascertaining that the mean stimulation frequency stays within preset limit values, wherein the limit values of the mean stimulation frequency can be individually preset in a range between 0.2 stimulation pulses per second and a maximum of 2 stimulation pulses per second, col 4 lines 5-7, wherein the appropriate range of parameters is programmable by a physician; pulse conservation means, col 2 lines 1-17 and col 4 lines 10-24 (i.e., the response amplification) for reducing the mean stimulation frequency depending on the maximum mean stimulation frequency preset in the evaluation unit, wherein the pulse conservation means comprise a computing unit 11 (control logic) for computing a stimulation pattern according to an equation which determines the stimulation pattern as a function of the mean stimulation frequency and wherein the number of stimulation pulses during a stimulation burst can be varied to reduce the mean stimulation frequency; and a monitoring unit 18 worn by the wearer of the device external to the body for displaying the mean stimulation frequency and for self-control of the patient, col 4 lines 28-29.

The method as described in claim 39 is rendered obvious, if not anticipated, by the elements described in claim 20.

Franberg et al. substantially describe the invention except for the memory unit. It would have been obvious, if not inherent, for a memory unit be included within the device, since it is well known in the implantable stimulation device art that memory units are included to store therapy programs and recorded physiological data.

Franberg et al. substantially describe the invention as claimed except for the mean stimulation frequency range. It would have been obvious to one of ordinary skill in the art at the time the invention was made to specify a specific range since it is taught by Franberg et al. that any variation in the stimulation rate should be between a minimum and maximum values (implying a range), that is programmable by a physician. Further it would have been obvious since it has been held by the Office that it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1995).

In regard to claim 21, the evaluation/determination stage is connected to control lines 12 through which signals identifying the current stimulation rate are transmitted, col 4 lines 20-24.

In regard to claim 22, the device of Franberg et al. necessarily contains an analysis unit since the stimulation signal is monitored to determine if the stimulation rate exceeded an upper threshold, col 4 lines 5-9.

In regard to claims 23-25, the enclosure 8 serves as the hosuing of the pacemaker and incorporates all elements of the pacemaker.

In regard to claims 26, the device of Franberg et al. has an external programming unit 18 which allows the physicians to program the pacemaker, and communicates with the telemetry unit 16 located within the enclosure of the pacemaker, col 4 lines 25-37.

In regard to claim 27, Franberg et al. discloses the claimed elements located in the pacemaker 10 itself and not in the external device 18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to locate the

elements in the external programmer, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japiske*, 86 USPQ 70.

In regard to claims 29 and 30, the device of Franberg et al. includes a telemetry unit 16 which is capable of sending and receiving data from the implantable device, and also includes a an activity sensor 7 which is known in the art for generating data relating to the position of the patient (i.e., supine, upright, etc).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 28 and 31, 32, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franberg et al. (US Patent no. 5,271,396) in view of Schulman (US Patent no. 4,232,679).

In regard to claim 28, Franberg et al. describe the invention substantially as claimed except for the external programming device containing some form of display. Schulman, in a similar field of endeavor, discloses an implantable and programmable human tissue stimulator that is programmed by an external controller 22, wherein the external controller 22 includes a digital display for displaying a parameter of the implantable device, col 9 lines 54-65 and col 24 lines 26-30. Therefore it would have

been obvious to one of ordinary skill in the art at the time the invention was made to modify the external controller of Franberg et al. with the external controller containing a display element taught by Schulman so that verification of the changes parameter can be made, col 9 lines 54-65.

In regard to claim 31, Franberg et al. describe the invention substantially as claimed except for the pulse generator creating biphasic pulses. The device of Schulman has a pulse generator that generates biphasic pulses, col 32 lines 60-63. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Franberg et al. to generate biphasic pulses since Schulman teaches that it was known in the art at the time.

In regard to claim 32, Franberg et al. describe the invention substantially as claimed except for transcutaneously recharging the power storage device located in the pacemaker housing. Schulman et al. teach that it is known in the prior art to recharge a power source of an implantable device by transmitting power from an externally located device, col 1 lines 10-21. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the external control unit of Franberg et al. to transmit power to an implantable device in order to recharge the power source since it is taught by Schulman and known in the art as an acceptable manner for restoring power to an implantable device without explanting it.

In regard to claims 36-38, Franberg et al. describe the invention substantially as claimed except for the variable nature of the stimulation parameters (i.e., frequency, amplitude, etc), though the external device of Franberg et al. is capable of adjusting

pacemaker parameters, col 4 lines 28-31. Schulman teaches that the stimulation parameters of frequency, amplitude, and pulse width are variable and programmable within an implantable device, col 1 lines 41-58 and col 5 line 57 – col 6 line 2 and col 6 lines 20-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Franberg et al. to programmable and variable parameters such as frequency, amplitude, and pulse width since Schulman teaches that these parameters must be variable since different disorders and different patients have different therapeutic needs, and it would be unfeasible to manufacture "tailor-made" devices for individual patients, therefore requiring that the parameters be adjustable.

10. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franberg et al. (US Patent no. 5,271,396).

In regard to claims 33 and 35, Franberg et al. describe the invention substantially as claimed except for the length of the defined time interval. It would have bee obvious to one having ordinary skill in the art at the time the invention was made to specify a certain time interval for the stimulation burst since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum and workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
Art Unit 3766

BTG

Carl H. Layno
Supervisory Patent Examiner
Art Unit 3766

CARL LAYNO
PRIMARY EXAMINER